Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte UFFE MORTENSEN, KJELD OLESEN, HENNING STENNICKE,
STEEN B. SORENSEN, and KLAUS BREDDAM

Appeal No. 2003-1307
Application No. 09/420,785

ON BRIEF

Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 24 and 25, which are all the claims pending in the application.

Claims 24 and 25 are reproduced below:

24. A modified carboxypeptidase Y, comprising
a substituted amino acid residue in at least one of positions N241 and L245, wherein the substituted amino acid residue has a negatively charged side chain, and
substitutions L178S and M398L,
wherein the modified carboxypeptidase Y is derived from the peptide having the sequence of SEQ ID NO: 4.

25. A method for transamidating a peptide substrate having a P_1 amino acid residue with a positively charged side chain and a P_3 amino acid residue with a positively charged side chain, the method comprising:

reacting the peptide substrate with a nucleophile in the presence of a modified carboxypeptidase Y;

wherein the modified carboxypeptidase is derived from the peptide having the sequence of SEQ ID NO: 4 and comprises: (a) at least one substitution in an S_1 subsite with an amino acid having a negatively charged side chain, (b) at least one substitution of an amino acid residue capable of interacting with a peptide substrate P_3 residue, wherein the substitution introduces an amino acid having a negatively charged side chain, and (c) substitutions L178S and M398L; and

wherein at least one substitution (a) and at least one substitution (b) are different.

No prior art is cited by the examiner.

GROUNDS OF REJECTION

Claims 24 and 25 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention.

We reverse.

DISCUSSION

The examiner emphasizes (Answer, page 4, emphasis original) that claim 24 comprises "a substituted negatively charged amino acid residue in at least one of positions N241 and L245 and substitutions L178S and M398L." Accordingly, the examiner finds (Answer, bridging sentence, pages 4-5), "[t]he genus of … modified carboxypeptidases Y encompass an infinite number of species having different structures and functions because 'comprising' is open claim language." According to the examiner (Answer, page 5), "the claim is not limited to substitutions at residues 241 and/or 245 (178 and 398) only and reads on an unlimited number of other substitutions negating, in effect, reference to SEQ ID NO:[ ]4." The examiner makes similar assertions with regard to the scope of claim 25.

We note, however, that the instant application is a divisional application of Application No. 08/807263, now United States Patent No. 5,985,627 ('627). Since the specification of the divisional application is the same as the instant specification, we refer to the specification and claims of the divisional application to illustrate that the appellants' specification provides an adequate description of the claimed invention. Claim 18 of the '627 patent is drawn to:

> A modified carboxypeptidase Y, comprising at least one substitution in an S_1 subsite with an amino acid having a negatively charged side chain and at least one substitution of an amino acid residue capable of interacting with a peptide substrate P_3 residue wherein the substitution introduces an amino acid having a negatively charged side chain wherein at least one substitution in the S_1 subsite and at least one substitution of an amino acid residue capable of interacting with a peptide substrate P_3 residue are different.

Claim 18 of the '627 patent appears to be of substantially greater scope than claim 24 now on appeal. Note, in contrast to appellants' claim 24, claim 18 of the '627 patent does not require that the "modified carboxypeptidase Y is derived from the peptide having the sequence of SEQ ID NO: 4."

We also note that three (N241, L245, and L178) of the four substituted amino acid residues are accounted for in claim 24 of the '627 patent:

> 24. The modified carboxypeptidase of claim 18, wherein at least one substitution in the S_1 subsite is at amino acid residue L178, W312, N241, or L245.

While the claims of the '627 patent do not include a limitation to L178S and M398L, we note that these limitations are disclosed at page 10, lines 4-5, page 16, lines 7 and 24-25 of appellants' specification.

Furthermore, regarding appellants' claim 25, we note that claim 1 of the '627 patent is drawn to:

> A method for transamidating a peptide substrate having a P_1 amino acid residue with a positively charged side chain and a P_3 amino acid residue with a positively charged side chain, the method comprising:
>
> reacting the peptide substrate with a nucleophile in the presence of a modified carboxypeptidase Y,
>
> wherein the modified carboxypeptidase comprises at least one substitution in an S_1 subsite with an amino acid having a negatively charged side chain and at least one substitution of an amino acid residue capable of interacting with a peptide substrate P_3 residue wherein the substitution introduces an amino acid having a negatively charged side chain wherein at least one substitution in the S_1 subsite and at least one substitution of an amino acid residue capable of interacting with a peptide substrate P_3 residue are different.

Claim 1 of the '627 patent appears to be of substantially greater scope than claim 25 now on appeal. Note, in contrast to appellants' claim 25, claim 1 of the '627 patent does not require that the "modified carboxypeptidase Y is derived from the peptide having the sequence of SEQ ID NO: 4."

We also note that the L178 and M398L substitutions are accounted for in at least claims 2 and 7 of the '627 patent:

2. The method of claim 1, wherein the modified carboxypeptidase comprises at least one substitution in the S_1 subsite at amino acid residue L178….

7. The method of claim 1, wherein the modified carboxypeptidase further comprises at least one substitution in an S_1' subsite selected from the group consisting of … M398L….

As discussed above, the specific L178S substitution is disclosed at page 10, lines 4-5 of appellants' specification.

Based on this evidence, we are unable to agree with the examiner's conclusion (Answer, page 8), "absent structural limitations on a modified

carboxypeptidase Y such as requiring the sequence of a modified carboxypeptidase Y to be highly homologous to SEQ ID NO:[ ]4, the description of said few selected positions is insufficient to visualize the entire structure of a modified carboxypeptidase Y." This conclusion appears to conflict with the claims of the '627 patent. In this regard, we note that a rejection using the rationale set forth by the examiner would appear to require the signature of the Group Director. Cf. MPEP § 2307.02. We note that the Group Director did not sign the Answer.

For the foregoing reasons, we reverse the rejection of claims 24 and 25 under 35 U.S.C. § 112, first paragraph.

REVERSED

Toni R. Scheiner Administrative Patent Judge	)
	) BOARD OF PATENT
Donald E. Adams Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Demetra J. Mills Administrative Patent Judge	)

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